

Sheet 1 of 3FORM PTO-1449  
(REV. 1-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.

910521.COC

SERIAL NO.

08/052,414

## LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT

Robert A. Ersek et al

FILING DATE

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## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	4093576		deWijn			
	AB	4186189		Shalaby et al			
	AC	4565580		Miyata et al			
	AD	4582640		Smestad et al			
	AE	4592864		Miyata et al			
	AF	4631188		Stoy et al			
	AG	4652441		Okada et al			
	AH	4803075		Wallace et al			
	AI	4822607		Balassa			
	AJ	4828827		Henderson et al			
	AK	4837285		Berg et al			

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	AI	3038047		Germany			
DSB	AM	0206726	12/86	Europe			
DSB	AN	2139898	11/84	United Kingdom			
DSB	AO	2227176	7/90	United Kingdom			
DSB	AP	0251695	1/88	Europe			

## OTHER PRIOR ART (Including Author, Title, Date, Patent No., Etc.)

	AR	Arnold, Godfrey E., "Vocal Rehabilitation of Paralytic Dysphonia" Archives of Otolaryngology, 62:1-17 (1965).
	AS	Balazs, E. A., et al, "The Replacement of the Vitreous Body in the Monkey by Reconstituted Vitreous and by Hyaluronic Acid", "Surgery of Retinal Vascular Diseases", Colloque, Amerstoort 1963. Mod. Probl. Ophthal., 4:230-232 (Karger, Basel/New York 1966).
	AT	Mentor O&O Inc. "Mentor Polytef Paste" package labeling.

EXAMINER

Debra S. Butts

DATE CONSIDERED

6-22-93

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



FORM PTO-1449  
(REV. 7-90)

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ATTY. DOCKET NO.  
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Sheet 2 of 3  
SERIAL NO.  
08/052,414

LIST OF PRIOR ART CITED BY APPLICANT  
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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	5007940		Berg et al			
	AB	4894231		Moreau et al			
	AC	4061731		Gottlieb			
	AD	4197846		Bucalo			
	AE	4212857		Balassa et al			
	AF	4341691		Anuta			
	AG	4424208		Wallace et al			
	AH	4469676		Hogmati			
DSB	AI	4678470	7/87	Nashef et al			
DSB	AJ	4863472	9/89	Tormala et al			
DSB	AK	5067965	11/91	Ersek et al			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	AL	0022724		Europe			
DSB	AM	86/03671	7/1986	PCT			
DSB	AN	87/05521	9/1987	PCT			
DSB	AO	88/07355	10/1988	PCT			
DSB	AP	88/06873	9/1988	PCT			

OTHER PRIOR ART (Including Author, Title, Date, Portmout Pages, Etc.)

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Sheet 3 of 3FORM PTO-1449  
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DSB	AA	4138382	2/1979	Polmanteer	—	—	
	AB						
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							YES	NO
	AL							
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# Attachment A

Prior Art for Information Disclosure Statement  
Serial No. 08/052,414, Filing Date: April 22, 1993

AUTHOR	TITLE	CITE/ISSUE DATE	REFERENCE/BOOK
	Product Bulletin (Price List)	3M Company, St. Paul, MN	3M Tracer Microspheres DSB
	Product Bulletin	Wilmington, DE	NEN-TRAC Microspheres, DUPONT NEN, DSB
	"Zyderm Collagen Implant".	24: 69-70 (1982). New Rochelle, NY: The Medical Letter, Inc. ( )	Med Lett Drugs Ther. DSB
Alvarez P., Balazs EA.	"Experimental Retinal Detachment in Owl Monkeys. Effect of Intravitreal Hyaluronidase Injection and Embolization of the Choroidal and Retinal Circulation".	12: 152-166 (1974)	Mod Probl Ophthalmol. DSB
Arnold, GE., and CB Stephens	"Laryngeal Injections with Polytef Paste".	59: 415-418 (October 1980)	Ear Nose Throat J. DSB
Arnold, Godfrey E.	"Vocal Rehabilitation of Paralytic Dysphonia".	Washington, D.C. (May 5-10, 1957)	Sixth International Congress of Otolaryngology, DSB
Arnold, Godfrey E.	"Alleviation of Aphonia or Dysphonia Through Intrachordal Injection of Teflon Paste".	72: 384-395 (1963)	Ann. Otol. Rhinol. Laryngol. DSB
Arnold, Godfrey E.	"Vocal Rehabilitation of Paralytic Dysphonia: VI. Further Studies of Intrachordal Injection Material".	73: 290-294 (1961)	Archives of Otolaryngology DSB

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AUTHOR	TITLE	CITE/ISSUE DATE	REFERENCE/BOOK
Ashley, FL and TD Rees	"An Injection Technique for the Treatment of facial Hemiatrophy".	35(6): 640-648 (1965)	Plast Reconstr Surg. DSB
Bailin, PL and MD Bailin	"Correction of Depressed Scars Following Mohs' Surgery: The Role of Collagen Implantation".	8:10 (1982)	J Dermatol Surg Oncol. DSB
Balazs, EA and E. Hultsch	"Replacement of the Vitreous with Hyaluronic Acid, Collagen and Other Polymers", Chapter 57, pp. 601-23 in	Springfield, Ill: Charles C. Thomas (1976) MW 250 C748a, 1974	Advances in Vitreous Surgery DSB
Balazs, Endre A., and D. Brendan Sweeney	"The Injection of Hyaluronic Acid and Reconstituted Vitreous into the Vitreous Cavity".	Chapter 36: Hyaluronic Acid and Reconstituted Vitreous, pp.371-376 (1968)	New & Controversial Aspects of Retinal Detachment, DSB
Berg, Solomon	"Polytef Augmentation Urethroplasty. Correction of Surgically Incurable Urinary Incontinence by Injection Technique".	107: 379-381 (Sept. 1973)	Arch Surg. DSB
Boedts, D., H. Roels and P. Kluyssens	"Laryngeal Tissue Responses To Teflon".	86: 562-567 (Nov. 1967)	Archives of Otolaryngology DSB
Boykin, William, Francisco R. Rodriguez, John P. Brizzolara, Ian M. Thompson and Eric J. Zeidman	"Complete Urinary Obstruction Following Periurethral Polytetrafluoroethylene Injection for Urinary Incontinence".	141: 1199-1200 (May 1989)	The Journal of Urology DSB

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Attachment A  
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AUTHOR	TITLE	CITE/ISSUE DATE	REFERENCE/BOOK
Brookler, Kenneth W. and Jack L. Pulec	"Auditory Tube Patency After Injection of Teflon Paste. An Investigation in Dogs".	90: 296-300 (September 1969)	Arch Otolaryngol DSB
Burke KE., G. Naughton, E. Waldo, and N. Cassai	"Bovine Collagen Implant: Histologic Chronology in Pig Dermis."	9(11): 889-895 (1983)	J Dermatol Surg Oncol. DSB
Carden, Edward, J. Pat Browder and Newton D. Fischer	"Teflon Injection of Vocal Cords Under General Anesthesia: A New Method".	54(6): 739-741 (Nov-Dec. 1975)	Anesthesia and Analgesia DSB
Castrow, FF, and EA Krull	"Injectable Collagen Implant-Update".	9(6): 889-893 (December 1983)	Journal of the American Academy of Dermatology DSB
Chvapil, M., RL Kronenthal, W. Van Winkle, JR.	"Medical and Surgical Applications of Collagen". in	London: Academic Press, 1973	International Review of Connective Tissue Research: DSB
Cooperman, L., and D. Michaeli	"The Immunogenicity of Injectable Collagen. I. A 1-year prospective Study".	10(4): 638-646 (April 1984)	J Am Acad Dermatol. DSB
<del>Cooperman, L., and D. Michaeli</del>	<del>"The Immunogenicity of Injectable Collagen. II. A Retrospective Review of Seventy-Two Tested and Treated Patients".</del>	<del>10(4): 647-651 (April 1984)</del>	<del>J Am Acad Dermatol.</del> Did Not Receive
Crary, William G., Murray Vexler and Karen Berliner	"The Abnormally Patent Eustachian Tube. Alterations in Psychological Status Resulting From Polytef Paste Injections".	105: 21-23 (January 1979)	Arch Otolaryngol DSB

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Attachment A  
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AUTHOR	TITLE	CITE/ISSUE DATE	REFERENCE/BOOK
Crumley, Roger L., Krzysztof Izdebski and Betty McMicken	"Nerve Transfer Versus Teflon" Injection for Vocal Cord Paralysis: A Comparison".	98: 1200-1204 (Nov. 1988)	Laryngoscope
Cummings, CW., John M. Fredrickson, Lee A. Harker, Charles J. Krause, David E. Schuller, Editors:		Update I., St. Louis: The C.V. Mosby Company, 1989	Otolaryngology-Head and Neck Surgery
Dedo, Herbert H., Robert D. Urrea and Lucie Lawson	"Intrachordal Injection of Teflon in The Treatment of 135 Patients With Dysphonia".	82: 661-667 (1973)	Ann. Otol.
Denlinger, JL., AA El-Mofty, and EA Balazs	"Replacement of the Liquid Vitreous with Sodium Hyaluronate in Monkeys. II. Long-term Evaluation".	30: 101-117 (1980)	Exp Eye Res.
Deporter, DA., A. Shiga, AH Helcher, and TP Howley	"The Effect of Bovine Skin Collagen (Zyderm) on the Healing of Experimental Defects in Rat Calvarium".	187: 353-363 (1985)	Prog Clin Biol Res.
Dunn, MW, Teruo Miyata, Kurt H. Stenzel, and Albert L. Rubin		19: 492-494 (1968)	Am. Coll. Surg. Forum
Ford, Charles N., DW Martin, and TF Warner	"Injectable Collagen in Laryngeal Rehabilitation".	94: 513-518 (April 1984)	Laryngoscope

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AUTHOR	TITLE	CITE/ISSUE DATE	REFERENCE/BOOK
Ford, Charles M., and DM Bless	"A Preliminary Study of Injectable Collagen in Human Vocal Fold Augmentation".	94(1): 104-112 (January 1986)	Laryngoscope DSB
Ford, Charles M., and DM Bless	"Clinical Experience with Injectable Collagen for Vocal Fold Augmentation"	96: 863-869 (August 1986)	Laryngoscope DSB
Frileck, SP.	"Part 1: The Management of Scars".	Vol. II, New York: Churchill Livingstone, 1987	Plastic Surgery of the Head and Neck DSB
Fritzell, B., O. Wallen and J. Sundberg	"Evaluation of Teflon Injection Procedures For Paralytic Dysphonia".	26: 414-421 (1974)	Folia Phoniat DSB
Goff, UE	<del>"Intracordal Polytef (Teflon) Injection: Histologic Study of Two Cases".</del>	<del>97: 371-372 (May 1973)</del>	<del>Arch. Otolaryngol</del>
Goff, Willard F.	"Laryngeal Adductor Paralysis Treated By Vocal Cord Injection of Bone Paste; A Preliminary Investigation".	41: 77-88 (1960)	Trans. Pacif. Coast Otol. Ophthalm. Soc. DSB
Goff, Willard F.	"Teflon Injection For Vocal Cord Paralysis".	90: 98-102 (July 1969)	Archives of Otolaryngology DSB
Goff, Willard F.	"Intracordal Polytef (Teflon) Injection: Histologic Study of Two Cases".	97: 371-371 (May 1973)	Archives of Otolaryngology DSB

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Attachment A

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AUTHOR	TITLE	CITE/ISSUE DATE	REFERENCE/BOOK
Grosh, SK., CW Hanke, DP DeVore, and DG Gibbons	"Variables Affecting the Results of Xenogenic Collagen Implantation in an Animal Model".	13(5 pt 1): 792-798 (November 1985)	J Am Acad Dermatol. DSB
Hanke, C. William	"Chapter 9: Dermal Filler Substances" in	St. Louis: The C.V. Mosby Company, 1986	Aesthetic Surgery of the Aging Face DSB
Harris, Harold E. Jr. and William A. Hawk	"Laryngeal Injection of Teflon Paste".	90: 194-197 (Aug. 1969)	Archives of Otolaryngology DSB
Hood, C. Ian, Frederick J. Schoen, Sylvia E. Coleman and Linda D. Hickley	"Assessment of Tissue Reactions to Biomaterials: A Model System Using the Foreign Body Response in the Mouse Lung to Intravenously Injected Divinyl Copolymer Beads".	18: 1031-1041 (1984)	Journal of Biomedical Materials Research DSB
Kamer FM, and MM Churukian	"Clinical Use of Injectable Collagen. A Three Year Retrospective Review".	110: 93-98 (Feb. 1984)	Arch Otolaryngol. DSB
Kaufman, Mark, Jorge L. Lockhart, Martin J. Silverstein and Victor A. Politano	"Transurethral Polytetrafluoroethylene Injection for Post-Prostatectomy Urinary Incontinence".	132: 463-464 (September 1984)	The Journal of Urology DSB
Kirchner, Fernando R., P.S. Toledo and D.J. Svoboda.	"Studies of the Larynx After Teflon Injection".	83: 350-354 (April 1966)	Archives of Otolaryngology DSB

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Attachment A  
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AUTHOR	TITLE	CITE/ISSUE DATE	REFERENCE/BOOK
Klein, AW, and DC Rish	"Injectable Collagen Update".	10(7): 519-522 (July 1984)	J Dermatol Surg Oncol. <i>D8B</i>
Klein, AW, and DC Rish	"Substances for Soft Tissue Augmentation: Collagen and Silicone".	11(3): 337-339 (March 1985)	J Dermatol Surg Oncol.
Knapp, IR	"Injectable Collage for Soft Tissue Augmentation".	60(3): 398-405 (September 1977)	Plast Reconstr Surg.
Knapp, Terry R., E. Luck, and JR Daniels	"Behavior of Solubilized Collagen as a Bioimplant".	23(2): 96-105 (August 1977)	Journal of Surgical Research
Labow TA, and DN Silvers	"Late Reactions at Zyderm Skin Test Sites."	35(2): 154-158 (February 1985)	Cutis <i>D8B</i>
Landes, E.	<del>Use and Experiences with Collagen in the Treatment of folds and scars. Die Anwendung von und Erfahrung mit Collagen bei der Behandlung von falten und Narben.</del>	<del>68(16): 1255-1269 (1985)</del>	<del>Z. Hautkr.</del>
Landman, MD., RW Strahan, and PH Ward	"Chin Augmentation with Polytef Paste Injection".	95(1): 72-75 (January 1972)	Arch Otolaryngol. <i>D8B</i>
LeVeen, Harry H. and J. Roland Barberio	"Tissue Reaction To Plastics Used In Surgery With Special Reference To Teflon".	129(1): 74-84 (1949)	Ann. Surg. <i>D8B</i>

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AUTHOR	TITLE	CITE/ISSUE DATE	REFERENCE/BOOK
Lewis, JR	"Alternative Methods of Correcting Soft-Tissue Defects", Chapter 76, pp. 535-537 in	Vol. 1, Boston: Little Brown and Company (1989)	The Art of Aesthetic Plastic Surgery
Lewis, Robert, Jorge L. Lockhart and Victor A. Politano	"Periurethral Polytetrafluoroethylene Injections in Incontinent Female Subjects With Neurogenic Bladder Disease".	131: 459-462 (March 1984)	The Journal of Urology
Lewy, Robert B.	"Tracheotomy Avoidance".	92:502 - 504 (Nov. 1970)	Arch. Otolaryng.
Lewy, Robert B.	"Experience With Vocal Cord Injection".	85: 440-450 (1976).	Ann. Otol.
Lewy, Robert B.	"Responses of Laryngeal Tissue to Granular Teflon in Situ".	83: 355-359 (April 1966)	Archives of Otolaryngology
Lewy, Robert B.	"Teflon Injection of the Vocal Cord: Complications, Errors and Precautions".	92: 473-474 (1983)	Ann. Otol. Rhinol. Laryngol.
Lim, KB, AJ Ball, and RCL Feneley	"Periurethral Teflon Injection: A Simple Treatment for Urinary Incontinence".	55: 208-210 (1983)	British Journal of Urology
Lockhart, Jorge L., R. Dixon Walker, Bert Vorstman and Victor A. Politano	"Periurethral Polytetrafluoroethylene Injection Following Urethral Reconstruction in Female Patients With Urinary Incontinence".	140: 51-52 (July 1988)	The Journal of Urology

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AUTHOR	TITLE	CITE/ISSUE DATE	REFERENCE/BOOK
Malizia, A.A. Jr., MK Devanjee, HM Reiman, SS Barham, RP Myers, TC Hammell, JR Sande, RC Benson, Jr., WJ Utz	"Polytef (Teflon) Migration After Periurethral Injection: Tracer and X-Ray Microanalysis Techniques in Experimental Study".	30: 330-334 (1983)	Trans Am Soc Artif Intern Organs DSB
Malizia, Anthony A. Jr., Herbert M. Reiman, Robert P. Myers, Jonathan R. Sande, Steven S. Barham, Ralph C. Benson, Jr., Minal K. Devanjee and William J.	"Migration and Granulomatous Reaction After Periurethral Injection of Polytef (Teflon)".	251(24): 3277-3281 (June 22/29, 1984)	JAMA DSB
Malizia, Anthony A., Herbert M. Reiman, Robert P. Myers, Jonathan R. Sande, Steven S. Barham, Ralph C. Benson, Jr., Minal K. Devanjee and William J. Utz	"Migration and Granulomatous Reaction After Periurethral Injection of Polytef (Teflon)".	251(24): 3277-3281 (June 22-29, 1984)	JAMA
Metouschek, E.	"Die Behandlung Des Vesikerenates -Reflexes Durch Transurethrale Einspritzung Von Teflonpaste- "Treatment of Vesicorenal Reflux by Transurethral Teflon Injections".	20: 263-264 (1981)	Urologe A.
Mittleman, Roger E. and John V. Marraccini	"Pulmonary Teflon Granulomas Following Periurethral Teflon Injection for Urinary Incontinence" (Letter to the Editor)	Vol. 127 (1983)	Arch Pathol Lab Med DSB

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AUTHOR	TITLE	CITE/ISSUE DATE	REFERENCE/BOOK
Nassar, W.Y.	"Polytef (Teflon) Injection of the Vocal Cords. Experience with Thirty-Four Cases".	91: 341-347 (1977)	J Laryngol Otol. <span style="float: right;">DSB</span>
Politano, VA	"Periurethral Teflon Injection for Urinary Incontinence".	5(2): 415-422 (June 1978)	Urol. Clin. North Am.
Politano, Victor A.	"Periurethral Polytetrafluoroethylene Injection For Urinary Incontinence".	127: 439-442 (March 1982)	Journal of Urology
Politano, Victor A., Michael P. Small, John M. Harper and Charles M. Lynne	"Periurethral Teflon Injection For Urinary Incontinence".	111: 180-183 (Feb. 1974)	The Journal of Urology
Resnik, SS	"Zyderm Collagen Implantation "letter and reply".	9(9): 711-712 (September 1983)	J Dermatol Surg Oncol. <span style="float: right;">DSB</span>
Rhodes, Buck A., Ilse Zolle, Julia W. Buchanan and Henry M. Wagner, Jr.	"Radioactive Albumin Microspheres for Studies of the Pulmonary Circulation".	92: 1453-1460 (June 1969)	Radiology
<del>Rubin, HJ</del>	<del>"Misadventures With Injectable Polytef (Teflon)".</del>	<del>101-2, 1975</del>	<del>Arch-Otolaryngol</del>
Rubin, Henry J.	"Misadventures With Injectable Polytef (Teflon)".	101: 114-116 (Feb. 1975)	Arch. Otolaryngol. <span style="float: right;">DSB</span>

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AUTHOR	TITLE	CITE/ISSUE DATE	REFERENCE/BOOK
Rubin, Henry J.	<del>Micrologic and High-Speed Photographic Observations On the Intracordal Injection of Synthetics.</del>	<del>70-900-921 (Nov-Dec 1966)</del>	<del>17th Annual Scientific Sessions: Amer. Acad. of Ophth. and Otolaryng.</del>
Rubin, Henry J.	"Histologic, High-Speed Photographic and Clinical Observations on the Intracordal Injections of Synthetics (A Motion Picture)".	p. 791 (Nov. 1965)	17th Annual Scientific Sessions: Amer. Acad. of Ophth. and Otolaryng.
Rubin, Henry J.	"Pitfalls in Treatment of Dysphonias By Intracordal Injection of Synthetics".	75(9): 1381-1397 (Sept. 1965)	The Laryngoscope
Sachse, H.	"Die Behandlung der Harninkontinenz mit der Sklerotherapie". Translation: "Treatment of Urinary Incontinence With Sclerosing Therapy Indications -- Results --	15(4): 225-244 (1963)	Urol. Int.
Sanfilippo F., J. Shelburne, and P. Ingram	"Analysis of a Polytef Granuloma Mimicking a Cold Thyroid Nodule 17 Months After Laryngeal Injection."	1: 471-475 (1980)	Ultrastruct Pathol.
Schell, JJ	"Polytef Injection for Nasal Deformity".	92: 554-559 (December 1970)	Arch Otolaryngol.
Schmittler, L., R. Baran, M. Arcey, L. Dubertret and M. Hoelen	Translation: "Cutaneous Responses to an Injectable Collagen Implant (Zyderm). Clinical, Histological and Ultrastructural Correlations After Intradermal Tests."	111(2): 135-145 (1984)	Ann Dermatol Venerol

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Schoen, Frederick J., Esperanza B. Kintanar, Rosalie G. Osol and Ellen Lee	"Pulmonary Reaction To Intravenously Injected Polymer Beads".	20: 709-721 (1986)	Journal of Biomedical Materials Research
Siegle, R.J., JP McCoy, Jr., W Schade, and WA Swanson	"Intradermal Implantation of Bovine Collagen. Humoral Immune Responses Associated with Clinical Reactions".	120: 183-187 (February 1984)	Arch Dermatol.
Spangler, AS	"New Treatment for Pitted Scars".	76: 708-711 (December 1957)	Arch Derm.
Spangler, Arthur S.	"Treatment of Depressed Scars with Fibrin Foam-Seventeen Years Experience".	1(4): 65-69 (December 1975)	The Journal of Dermatologic Surgery:
Stegman SJ, and IA Tronovitch	"Implantation of Collagen for Depressed Scars".	6(6): 450-453 (June 1980)	J Dermatol Surg Oncol.
Stephens, Charlene B., Godfrey E. Arnold and John W. Stone	"Larynx Injected With Polytef Paste".	102: 432-435 (July 1976)	Arch Otolaryngol
Stone, John W. and Godfrey E. Arnold	"Human Larynx Injected With Teflon Paste: Histologic Study of Innervation and Tissue Reaction".	86: 550-561 (Nov. 1967)	Arch Otolaryng.
Stone, John W., Godfrey E. Arnold and Charlene B. Stephens	"Intracordal Polytef (Teflon) Injection: Histologic Study of Three Further Cases".	91: 568-574 (June 1970)	Archives of Otolaryngology

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AUTHOR	TITLE	CITE/ISSUE DATE	REFERENCE/BOOK
Swanson, MA., JG Stoner, RJ Siegle, and AR Solomon	"Treatment Site Reactions to Zyderm Collagen Implantation".	9(5): 377-380 (May, 1983)	J Dermatol Surg Oncol.
Toomey, James M. and Bruce S. Brown	"The Histological Response To Intracordal Injection of Teflon Paste".	77: 110-120 (1967)	Laryngoscope
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